

Via Valenzana di Sopra, 60 Bozzano - 55054 Massarosa (Lu) - Italy Tel. +39 0584 938305 - 93363 - 938306 Fax +39 0584 937167 asadental@asadental.it www.asadental.it - www.asadental.com



# GENERAL TERMS AND CONDITIONS OF SALE

# Asa Dental S.p.A.

These General Terms and Conditions of Sale (the "Conditions") govern the supply of products and accessories (the "Products") by the Supplier to the Buyer or Distributor, as below identified.

• "Supplier/Manufacturer": Asa Dental S.p.A.			
	Legal address: Via Valenzana di Sopra, 60 – 55054 Bozzano, Massarosa (LU)		
	Authorized Representative: Alessandro Malfatti, CEO		
•	"Buyer/Distributor":		
	Legal address:		
	Authorized Representative:		

Hereinafter individually referred to as the "Party" and jointly as the "Parties".

By signing this document, the Parties accept and agree to be bound by the Conditions set forth below. These Conditions apply to all present and future purchase orders, unless otherwise expressly agreed in writing by both Parties. The Parties expressly undertake to comply with all clauses of these General Terms and Conditions of Sale in their entirety.

Documento	Issue Date	Version
General Terms and Conditions of Sale	18/07/2025	0

EXPORT DIVISION:

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STABILIMENTI/PLANTS:

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Via delle Piagge, 1/A - Marlia - 55014 Capannori (Lu)

Via Fierla, 13 - Z.I. - 33085 Maniago (Pn)

BANCHE/BANKS:

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#### **Subject** 1

1.1 These general terms and conditions of sale (the "Conditions") apply to all supply contracts for products and accessories manufactured and/or sold by Asa Dental S.p.A., with its registered office at Via Valenzana di Sopra, 60, Bozzano 55054 Massarosa (LU) (the "Products"). Under no circumstances shall Asa Dental be bound by any general conditions of the Buyer.

#### 2 **Orders**

- 2.1 The Buyer's order becomes binding 2 days after Asa Dental's order confirmation is sent. Thereafter, any cancellation/modification of an order already accepted by Asa Dental shall be considered ineffective unless Asa Dental expressly consents in writing. Any supply contract for the Products shall be deemed conventionally concluded at Asa Dental's headquarters.
- 2.2 Each purchase order submitted by the Buyer must have a minimum value of €150.00 (one hundred fifty/00), excluding VAT and transport costs. Orders below this amount may be suspended by the Supplier until the total value reaches the minimum threshold indicated above.

#### **Prices** 3

3.1 Unless otherwise agreed in writing, all price indications are EX-Works - Lucca (Italy) (Incoterms 2020), based on Asa Dental's current price list at the time of order confirmation. As Dental reserves the right to modify product prices with 30 days prior written notice. Payment for the Products shall be made under the conditions agreed upon in writing on a caseby-case basis, however, upon written notice, Asa Dental shall be entitled at any time to adjust the prices of the Products in the exceptional event of any significant increase in the cost of raw materials, components, energy, or other productionrelated costs.

# **Delivery Terms**

4.1 All delivery dates are purely indicative. Delivery time is not essential, and under no circumstances shall the Buyer be entitled to cancel the order or claim any compensation for late delivery. The Buyer undertakes to promptly collect the Products upon simple notice of availability from Asa Dental and, in any case, within 5 working days from such notice. Payment terms are agreed upon in writing on a caseby-case basis. In the event of outstanding products pending delivery, such products shall be shipped as soon as they become available in the next scheduled shipment. Under no circumstances, including but not limited to disposable products, shall such items be shipped separately Free Carrier to the Buyer.

# **Payment**

- 5.1 Under no circumstances shall the Buyer suspend or delay payment for the Products, including cases where the Buyer raises complaints.
- 5.2 In the event of late payment, Asa Dental shall be entitled to interest under the applicable Italian laws on late payment in commercial transactions without prejudice to Asa Dental's right to claim further damages and apply the remedies outlined in Article 11.

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# 6 Compliance with European Regulations

As a Dental guarantees that the Products comply with applicable laws and regulations in **Europe** at the time of order confirmation but does not guarantee compliance with laws/regulations in the place where the products are to be sold/installed. Unless otherwise agreed in writing, As Dental is not obliged to modify the Products to comply with any non-European laws or regulations; it is the sole responsibility of the Buyer to ensure such compliance.

# 7 Medical Device Batch Traceability

- 7.1 **Traceability Obligation:** the Distributor undertakes to ensure full traceability of each distributed medical device, in accordance with Regulation (EU) 2017/745 (MDR) and the applicable regulations concerning medical devices. This traceability must include the recording and storage of details related to the batch of origin for each distributed device.
- 7.2 **Documentation and Record Keeping:** the Distributor must maintain accurate and easily accessible documentation that enables the traceability of medical devices from the manufacturer to the final recipient. This documentation must be retained for a minimum period of 10 years as required by current regulations.
- 7.2.1 <u>Communication Obligation: upon request by the competent authorities or the Manufacturer, the Distributor must promptly provide all necessary information to ensure traceability of the medical device, including batch numbers, distribution dates, and other data related to the movement of the devices.</u>
- 7.2.2 The Distributor is also required to immediately report to the Manufacturer any complaints and/or reports from healthcare professionals, patients, or users concerning alleged incidents related to the device. This includes the obligation to maintain and update a register of complaints concerning non-conforming devices as well as recalls and withdrawals.
- 7.2.3 The Manufacturer has the right to examine complaints by requesting more detailed information and, if necessary, by verifying the Distributor's customer.
- 7.2.4 <u>In case of complaints or non-conformities, the Distributor is also obliged to implement the actions communicated by the Manufacturer and to report back the results of the actions taken.</u>
- 7.3 Non-Compliance: the Distributor acknowledges that failure to comply with the above traceability obligations may result in legal liability and penalties, in accordance with the MDR Regulation and applicable local laws. Any negligence in this regard must be promptly reported to the Manufacturer.
- 7.4 Storage and Transport Conditions: for the period during which a device is under the Distributor's responsibility, the storage and transport conditions must comply with those established by the Manufacturer.
- 7.5 Obligation Not to Modify: the Distributor, under its own responsibility, declares that it will not make any modifications to: the products manufactured by the Manufacturer, the elements related to the affixing of the CE marking carried out in compliance with Article 20 of Regulation (EU) 2017/745, or the content of the instructions for use.
- 7.6 Post-Market Activities: both parties commit to carrying out the market surveillance activities required by Regulation (EU) 2017/745, as well as post-market surveillance of the medical devices on an annual basis. The purpose is to mutually inform each other of: any issues related to the safety and performance of the medical devices, any considerations concerning the clinical use of the devices, market complaints, and any incidents or near misses.

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7.7 Promotional Activities: the Distributor's promotional activities must be fully transparent regarding the characteristics, uses, and benefits of the medical device and must comply with the information contained in the device's technical data sheets or any other materials provided by the Manufacturer. The Distributor also undertakes to respect and maintain the intended use of the medical device as defined by the Manufacturer.

# International Shipping documents, Ex-Works Delivery

In the case of international road shipments under Ex-Works (EXW) delivery terms, the Buyer undertakes to correctly manage and complete all details related to the shipment, including entering the necessary information into the CMR system for the completion of customs and logistics formalities, as well as managing the transportation contract. i.e.:

- CMR Completion Obligation: the Buyer is responsible for the correct completion and accuracy of the information entered into the CMR in connection with the shipment of the medical device. The Buyer agrees to provide all required information and to complete the CMR form accurately and in a timely manner.
- Authorization for CMR Signature by Asa Dental: if the Buyer fails to complete or incorrectly completes the CMR form within the established deadlines, the Buyer expressly agrees and authorizes Asa Dental to sign and complete the CMR form on the Customer's behalf. This signature will be performed solely for the purpose of ensuring the proper completion of the shipment and the execution of customs or logistics formalities, without implying any additional liability for the Manufacturer.
- Customer Responsibility: the Buyer acknowledges that failure to complete the CMR or errors in the provided information may lead to shipping delays, customs issues, or penalties, and undertakes to be liable for any consequences arising from such omissions or errors. As aDental shall not be held liable for any damages resulting from the Buyer's failure to properly complete the CMR.

#### 9 **Import Customs Declaration**

The Buyer undertakes to make available to the Manufacturer a copy of the customs declaration related to the importation of the medical devices, no later than 30 days from the date of customs clearance. This document must be provided in digital format (PDF) or any other format agreed upon by the Parties, and must include all necessary information to clearly identify the shipment, recipient, and customs reference.

### 10 Buver's Liability

The Buyer shall indemnify and hold Asa Dental harmless from any claims, demands, legal actions, or compensation requests concerning the obligation to ensure the Products' compliance with applicable laws, safety regulations, and/or technical standards in the country of sale.

### Asa Dental's Rights in Case of Late Payment

11.1 In case of non-payment or late payment, Asa Dental may immediately and without notice: (i) terminate the contract concerning undelivered Products; (ii) delay execution of the Buyer's orders, even if already accepted; (iii) suspend Product deliveries until all outstanding debts to Asa Dental are settled.

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11.2 As Dental may immediately suspend and/or terminate supply contracts if the Buyer undergoes liquidation or any insolvency procedure or if the Buyer's financial condition deteriorates to the point of jeopardizing contractual obligations, without prejudice to Asa Dental's right to claim damages.

# 12 Warranty and Return Policy

- 12.1 Asa Dental guarantees that all its Products are free from manufacturing defects for 24 months from the delivery date (the "Warranty").
- 12.2 The Buyer acknowledges that the Warranty is strictly limited to manufacturing defects and does not cover, for example: Products lacking identifying traceability data linking them to Asa Dental; Damage due to transport, loading/unloading, improper use or treatment, inadequate storage or maintenance; non-compliance with Asa Dental's usage instructions, use of unsuitable raw materials, Buyer-supplied or third-party components, normal wear and tear, or unauthorized repairs/replacements.
- 12.3 Asa Dental's maximum liability under the Warranty is limited to the price paid by the Buyer for defective Products. Asa Dental shall not be liable for lost profits, incidental, consequential, or indirect damages suffered by the Buyer. The sole remedy available to the Buyer under the Warranty is at Asa Dental's discretion: repair or replacement of the defective Product. As Dental reserves the right to inspect defective Products to determine if they are covered by the Warranty.
- 12.4 The Buyer must notify Asa Dental of any defects in writing within 8 days of delivery for visible defects and within 8 days of discovery for hidden defects, and in any case within the Warranty period, or the Warranty shall lapse.
- 12.5 The Buyer may withdraw from an individual supply contract within 14 days of receiving the Products by providing written notice to Asa Dental. The Buyer shall return the Products at their own expense. Refunds will be issued only if the Products are intact and fit for their intended purpose. If eligible, Asa Dental will issue a credit note (CN), reduced by 20% of the total Product value to cover inspection costs. The right of withdrawal is excluded for: Custom-made or personalized products, sealed products that cannot be returned for hygiene or health protection reasons if opened after delivery.
- 12.6 If the withdrawal is not made in accordance with this article, it shall not result in contract termination or entitlement to a refund.

# 13 Force Majeure

As aDental shall not be liable for any failure to fulfill contractual obligations due to force majeure events, such as delays or non-delivery by suppliers, strikes, epidemics, terrorism, energy shortages, war, embargoes, riots, fires, sabotage, natural disasters, government actions, or lockouts. The Buyer may not invoke force majeure to justify non-payment of amounts due to Asa Dental.

# 14 Confidentiality and Intellectual Property Rights

- 14.1 For 5 years from receipt, the Buyer shall keep confidential all information learned from Asa Dental during the contractual relationship.
- 14.2 The Buyer acknowledges that Asa Dental retains full and exclusive ownership of know-how, trade secrets, trademarks, trade names, patents, inventions, and other industrial property rights related to the Products ("IP Rights"). No supply contract

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shall be construed as transferring or granting IP Rights to the Buyer. The Buyer shall not engage in any activities that directly or indirectly infringe upon Asa Dental's IP Rights or constitute unfair competition.

# 15 Applicable Law and Jurisdiction

- 15.1 All supply contracts concluded by Asa Dental shall be governed exclusively by Italian law, expressly excluding the application of the 1980 Vienna Convention on the International Sale of Goods.
- 15.2 Any dispute between the Buyer and Asa Dental arising from the supply of Products shall be subject to the exclusive jurisdiction of the Court of Lucca, Italy.

# **Signatures**

In witness whereof, the Parties hereto have read, understood, and signed these General Terms and Conditions of Sale. Each Party acknowledges and agrees to be legally bound by its provisions.

Date and place: Approval Date and place:

Thursday, 24 July 2025

Massarosa, Lucca – Italy

Place

The Company The Buyer

ASA DENTAL S.p.A. Name of the Company

The Legal Representative

Mr. Alessandro Malfatti

The Legal Representative

Authorized Representative

CEO | Asa Dental S.p.A. Position in the company

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